

PATENT 3523/2/US
Ser. No. 09/933,366
Page 2

I. INTRODUCTION

Claims 1-30 are pending in the present application. Applicant proposes to amend claims 22 and 30, as described herein below.

All of the pending claims were rejected, under 35 U.S.C. §103(a), over Barbachyn *et al.* (U.S. Pat. No. 5,688,792) in view of Bartoli *et al.* (U.S. Pat. No. 5,646,294) in a previous Office Action, dated December 31, 2002, a "Final" Office Action. Applicant thanks the Examiner for withdrawing that rejection and the finality of the Office Action in the Office Action, dated August 1, 2003. Two new grounds of rejection were set forth in the latest Office Action. Applicant respectfully traverses both grounds of rejection, in view of the following amendment and remarks.

II. AMENDMENT

Please amend claims 22 and 30 as follows.

1. A pharmaceutical composition for administration to a subject having or at risk of infective disease, the composition comprising an aqueous carrier having in solution therein (a) an oxazolidinone antimicrobial drug concentration that is an effective concentration above the practical limit of solubility of the drug in a substantially isotonic aqueous solution at a physiologically compatible pH, and (b) a pharmaceutically acceptable cyclodextrin compound in a concentration sufficient to maintain the drug in solution at such a drug concentration.
2. The composition of Claim 1, wherein the drug concentration is a therapeutically effective amount.
3. The composition of Claim 1, wherein the drug concentration is a prophylactically effective amount.
4. The composition of Claim 1 that is suitable for parenteral administration.
5. The composition of Claim 1 that is suitable for intravenous injection or infusion.
6. The composition of Claim 1 wherein the concentration of the drug is about 3 to about 100 mg/ml.
7. The composition of Claim 1 wherein the concentration of the drug is about 4 to about 40 mg/ml.
8. The composition of Claim 1 wherein the concentration of the drug is about 5 to about 10 mg/ml.
9. The composition of Claim 1 wherein the oxazolidinone antimicrobial drug is selected from the group consisting of linezolid, N-((5S)-3-(3-fluoro-4-(4-(2-fluoroethyl)-3-oxopiperazin-1-yl)phenyl)-2-oxooxazolidin-5-ylmethyl) acetamide, (S)-N-[[3-[5-(3-pyridyl)thiophen-2-yl]-2-oxo-5-oxazolidinyl]methyl] acetamide, (S)-N-[[3-[5-(4-pyridyl)pyrid-2-yl]-2-oxo-5-oxazolidinyl]methyl] acetamide hydrochloride; and N-[[5S)-3-[4-(1,1-dioxido-4-thiomorpholinyl)-3,5-difluorophenyl]-2-oxo-5-oxazolidinyl]methyl]acetamide.
10. The composition of Claim 1 wherein the oxazolidinone antimicrobial drug is linezolid.

PATENT 3523/2/US

Ser. No. 09/933,366

Page 4

11. The composition of Claim 1 wherein the oxazolidinone antimicrobial drug is N-[[[(5S)-3-[4-(1,1-dioxido-4-thiomorpholinyl)-3,5-difluorophenyl]-2-oxo-5-oxazolidinyl)methyl]acetamide.
12. (Previously amended) The composition of Claim 1 wherein the cyclodextrin compound is selected from the group consisting of α -cyclodextrin, β -cyclodextrin, γ -cyclodextrin, alkylcyclodextrins, hydroxyalkylcyclodextrins, carboxyalkylcyclodextrins and sulfoalkylether cyclodextrins.
13. The composition of Claim 1 wherein the cyclodextrin compound is selected from hydroxyalkyl- β -cyclodextrins and sulfoalkylether- β -cyclodextrins.
14. The composition of Claim 1 wherein the cyclodextrin compound is selected from hydroxypropyl- β -cyclodextrin and sulfobutylether- β -cyclodextrin.
15. The composition of Claim 1 wherein the cyclodextrin compound is sulfobutylether- β -cyclodextrin.
16. The composition of Claim 1 wherein the cyclodextrin compound is present at a concentration of about 1 to about 500 mg/ml.
17. The composition of Claim 1 wherein the cyclodextrin compound is present at a concentration of about 5 to about 200 mg/ml.
18. The composition of Claim 1 wherein the cyclodextrin compound is present at a concentration of about 10 to about 100 mg/ml.
19. The composition of Claim 1 wherein the cyclodextrin compound is present at a concentration of about 20 to about 50 mg/ml.
20. The composition of Claim 1 wherein the cyclodextrin compound is present at a concentration of about 100 to about 500 mg/ml.
21. The composition of Claim 1, further comprising a buffering agent and/or an agent for adjusting osmolality in amounts whereby the solution is substantially isotonic and has a physiologically acceptable pH.
22. (Presently amended) A method of treating or preventing an infective disease in a subject

arising from infection by one or more gram-positive bacteria, anaerobic organisms, or acid-fast organisms, the method comprising administering to the subject the composition of Claim 1 in a therapeutically or prophylactically effective daily dose.

23. The method of claim 22, wherein the composition is diluted in a pharmaceutically acceptable liquid prior to being administered to the subject.
24. The method of Claim 22 wherein the subject is a human subject.
25. The method of Claim 24 wherein the oxazolidinone antimicrobial drug in the composition is linezolid.
26. The method of Claim 25 wherein the daily dose is about 100 to about 1000 mg of linezolid.
27. The method of Claim 23 wherein the composition is administered parenterally.
28. The method of Claim 23 wherein the composition is administered by intravenous injection or infusion.
29. The method of Claim 22 wherein the oxazolidinone antimicrobial drug is N-[[[(5S)-3-[4-(1,1-dioxido-4-thiomorpholinyl)-3,5-difluorophenyl]-2-oxo-5-oxazolidinyl)methyl]acetamide.
30. (Presently amended) A method of use of a composition of Claim 1 in manufacture of a medicament for treating or preventing an infective disease arising from infection by one or more gram-positive bacteria, anaerobic organisms, or acid-fast organisms.